DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

g1179d

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

April 23, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 54

Jeffrey Ettinger
President
Earl B. Olson Feed Mill
Division of Jennie-O Foods, Inc.
2505 Willmar Avenue SW
Willmar, Minnesota 56021

Dear Mr. Ettinger:

An inspection of your medicated feed mill located at 21 Third Street, Swanville, MN, conducted by a Food and Drug Administration (FDA) investigator on March 6-7 and 13, 2001, found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000, Animal Proteins Prohibited in Ruminant Feed (21 CFR 589.2000). The regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being manufactured and/or distributed by this facility to be misbranded within the meaning of Section 403(f) of the Federal Food, Drug and Cosmetic Act (the Act).

Our investigation found a failure to label your products with the required cautionary statement, "Do Not Feed to Cattle or Other Ruminants." Some of your products manufactured in Mixer #2 completely lacked the required cautionary statement. Other labels provided to our investigator contained an incomplete statement, i.e., "Do Not Feed to Ruminants." The FDA suggests the complete cautionary statement be distinguished by different type size or color or other means of highlighting the statement so that it is easily noticed by a purchaser.

Additionally, the inspection also found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (21 CFR 225). Deviations from CGMPs cause medicated feeds being manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Our investigation revealed:

- There are no approved master record files for several feeds.
- Master record files lack complete manufacturing procedures, e.g., mixing steps and mixing times.
- Daily drug inventory records fail to account for all animal drugs in the facility.
- Production records are not being retained.
- Feed labels are not handled in a manner to prevent mix-ups and to assure that correct labels are used.

The above CGMP deviations are examples only. Please see the form FDA-483 issued to Duane L. Johnson, General Manager, for more details (copy enclosed).

When the form FDA-483 was issued by our investigator, the individual observations were annotated with the statements "Corrected and Verified" or "Corrected." These annotations are not meant to imply that corrective actions taken by the company during the inspection fully address the systemic CGMP and labeling problems observed during the inspection. We will conduct a follow-up inspection in the near future to evaluate the effectiveness of corrections made in response to the form FDA-483 and this Warning Letter.

The above is not intended to be an all-inclusive list of CGMP and labeling violations. As a manufacturer of medicated and non-medicated feeds you are responsible for ensuring that your overall operation and the products you manufacture and distribute are in compliance with the law. We have enclosed a copy of the FDA's Small Entity Compliance Guide to assist you in complying with 21 CFR 589.2000, Animal Proteins Prohibited from Use in Ruminant Feed.

You should take prompt action to correct these violations and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction and/or notice of opportunity for a hearing on a proposal to withdraw approval of your mill license under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2).

This letter constitutes official notification under the law. Based on the results of the March 6-7 and 13, 2001, inspection, evaluated together with the evidence before FDA when the mill license was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feed are inadequate to assure and preserve the identity, strength, quality and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be taken within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,

Cheryl A. Bigham
Acting Director
Minneapolis District

TGP/ccl

Enclosures: FDA-483, 3/13/01
FDA Small Entities Compliance Guide, 21 CFR 589.2000

xc: Duane L. Johnson
Manager
Earl B. Olson Feed Mill
21 Third Street
Swanville, MN 56382